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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 209,541	12 11 1998	ANNA GUTOWSKA	E-1537-CIP	6863

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EXAMINER

MULLIS, JEFFREY C

ART UNIT PAPER NUMBER

1711

DATE MAILED: 11 28 2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/209,541	Applicant(s) GUTOWSKA, ANNA	
	Examiner Jeffrey C. Mullis	Art Unit 1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 27 August 2001.
- 2a) ☒ This action is **FINAL**.
- 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 13-30 and 37-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 31-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other

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All remaining rejections and/or objections follow.

Claims 1-12 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation that the amount of hydrophilic comonomer is greater than or equal to about 1% was not broadly disclosed in the specification as filed. This limitation is therefore new matter.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4 and 9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sassi et al. (USP 5,631,337).

See the Examples in column 7 where two hydrophilic acrylamides are used to produce a copolymer.

See the previous Office action at the paragraph bridging pages 3 and 4 et seq.

Claims 1-9 and 12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bae et al. (USP 5,262,055).

Note Example 2 in column 3 for use of two hydrophilic acrylamide comonomers to produce a copolymer. See page 4 at the last complete paragraph of the previous Office action et seq.

Claims 1-12 and 31-36 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hoffman et al. (USP 5,998,588).

See Example 3 in column 33 where a copolymer is produced from an isopropylacrylamide and acrylic acid. Note the last

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complete paragraph on page 5 et seq. of the previous Office action.

Applicant's arguments filed 8-27-01 have been fully considered but they are not deemed to be persuasive.

Applicant argues that support for applicant's amount of comonomer of \geq about 1 mole percent is found at page 9 line 4. However page 9 line 4 specifically says that about 1% by mole or more comonomer may be used "when the hydrophilic comonomer is AAc" and the thermosensitive comonomer is NiPAAm. There is no broad disclosure in applicant's specification regarding the lower limit of comonomer.

With regard to the election, applicant points out that Paper 4 recites that upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim. However no generic claim has been allowed. In any case, no claims have been withdrawn as being drawn to a non-elected species.

With regard to Sassi, applicant argues that Sassi's polymers are linear and nonionic while applicant's are ionic. However no such limitation appears in the claims. Applicants argue that their claims distinguish over Sassi based on the fact that applicant's claims recite the presence of a hydrophilic

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comonomer. However Sassi's polymers are copolymers and acrylamide as used by Sassi is hydrophilic.

Applicant argues that the Examiner has not addressed the additional limitations in claims 2-11. The Examiner does not agree with this since all that is required of the remaining rejected claims is the presence of a non-specific N-alkyl substituted acrylamide or methacrylamide such as is embraced by the acrylamide monomers of the Examples of patentees. Note that column 7 lines 30-35 discloses that acrylylglycinamide may be used, embraced by applicant's N-alkyl substituted acrylamide. It is noted that applicant's definition of alkyl is implicitly much broader than ordinarily used in the art given that applicant's definition includes such materials as acryloylpyrrolidine and therefore appears to embrace any N-carbon substituted acrylamide. The only other limitations related to the monomer is claim 2 which recites that "said amount" is about 1.6 mole percent. This claim however does not appear to limit claim 1 in any reasonable manner given that the material to which "said amount" refers to is not recited nor is the amount on which the amount based on recited.

With regard to Bae et al. '055, applicant argues that the instant claims require a hydrophilic comonomer. However Example 2 of Bae et al. specifically utilizes two unsaturated amide comonomers, both of which are hydrophilic. Therefore it is

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proper to conclude that Bae et al.'s composition reasonably possesses applicant's characteristics. Applicant argues that the Examiner has not pointed out the limitations of the dependent claims. However the Examiner does not agree with this. The only additional limitations of the dependent claims pertain to the identity of specific monomers which are taught by the reference. For instance, Example 2 of the reference utilizes N-isopropyl methacrylamide as well as an acrylamide derivative required by the dependent claims. With regard to claim 2, the Examiner's position is the same as set out above regarding Sassi et al.

With regard to Hoffman et al., applicant's independent claim recites a copolymer of an acrylamide monomer and a hydrophilic comonomer. It is noted that previously the claims did not clearly require the presence of two comonomers but in any case at present, the two comonomers are clearly present in the copolymers of the Examples of Hoffman et al. Note Example 3 for instance of Hoffman et al. which utilizes acrylic acid which is a highly hydrophilic comonomer along with N-isopropylacrylamide which is recited by the dependent claims. It is noted that the materials of patentees are present in water. Therefore it is proper to conclude that the patent composition contain applicant's characteristics. With regard to the dependent claims, again the Examiner's position with regard to claim 2 is the same as with regard to the other two rejections under 35 U.S.C. § 102/103.

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With regard to the other dependent claims, these further limit the comonomers used to specific comonomers. However the combination of N-isopropylacrylamide/acrylic acid embraces all of the comonomers of the dependent claims. With regard to claim 10, a phosphate buffer is used by the Examples of patentees.

Applicant's specific comonomers are taught by the reference and therefore it reasonably appears that applicant's characteristics would be inherent in the reference. Applicant's own Example 1 utilizes an isopropylacrylamide co-acrylic acid copolymer. It cannot be seen how this copolymer can possibly be different than the copolymer of the reference since the same materials are used. It seems to be little question but that the copolymer of Hoffman et al. has identical properties to that of applicant given that the copolymers utilized are identical. There is no missing descriptive matter in the references which pertain to the material features of applicant's invention. Therefore it is reasonable to assume that applicant's characteristics are inherent in the reference.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

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A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication should be directed to Jeffrey Mullis at telephone number (703) 308-2820.

J. Mullis:cdc

November 13, 2001

Jeffrey Mullis
Primary Examiner
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